

REMARKS

Reconsideration of the present application is requested. Claims 192-197 and 209-224 were subject to substantive review. Applicant appreciates the indication of patentability of claims 216 and 218-221 and the entry of the previously submitted terminal disclaimer.

Claims 192-215, 217 and 222-224 were subject to new grounds of rejection centered upon Patent No. 5,702,454 to Baumgartner. In particular, independent claims 192 and 212 were rejected as anticipated by Baumgartner. With respect to claim 192, it is believed that Baumgartner does not disclose each step of the claimed method. In particular, claim 192 recites introducing top and bottom elements, and introducing intermediate elements "consecutively between said top element and said bottom element." Thus, the method of claim 192 first requires the presence of a top element and a bottom element, and then requires that each of the intermediate elements be consecutively inserted between these pre-positioned top and bottom elements. In contrast, Baumgartner discloses jamming ball after ball into the disc cavity. There is no pre-positioned top and bottom element in Baumgartner. While some of the elastic ball support elements may end up on top or bottom, they do so randomly and only when the cavity has been filled to some degree. Baumgartner does not disclose deliberately introducing a top elastic ball and a bottom elastic ball and then introducing the ensuing balls between those top and bottom elastic balls. By necessity, and as depicted in FIG. 1, the elastic ball support members in Baumgartner must fill the disc space from the rear of the space toward the access opening.

While it is believed that claim 192 as previously presented sets forth this aspect of the claimed method, Applicants have amended the claim to more clearly recite an order to the introducing steps. Specifically, the claim has been amended to state that first the top and bottom elements are introduced and then the intermediate elements are consecutively introduced between the pre-positioned top and bottom elements. Even if some of the elastic ball support elements in Baumgartner can be regarded as top and bottom elements, these elements are not first introduced, and the subsequently introduced ball elements are not then introduced between top and bottom elements. There is nothing in Baumgartner that contemplates anything more than the randomly packed support elements shown in FIGS. 1 and 2 of that reference.

It is therefore believed that claim 192 as amended is patentable over Baumgartner, along with its dependent claims 193-211 and new claim 225. It can further be noted that the dependent claims are patentable on their own merits. For instance, claim 193 follows the language of claim 192 in that "each" of the intermediate elements is introduced by sliding between the top and bottom elements. It is apparent that the majority of the elastic ball elements in Baumgartner are not each introduced in this manner.

Claim 194 was said to be anticipated by Baumgartner by the ducts 14 and support 20. However, claim 194 defines the intermediate element itself as configured for interlocking coupling with at least the top element. The ducts 14 in the ball elements of Baumgartner cannot interlock with each other. The presence of a third component, the support 20, does not render the structure of the ball elements "interlocking". Thus, claim 194 cannot be anticipated by Baumgartner. The same argument applies to claim 195, which defines a second intermediate element configured for interlocking with the bottom element and the first intermediate element.

Claims 196 and 197 were said to be obvious in view of Baumgartner on the grounds that "mere relocation of parts of an invention involves only routine skill in the art." While Baumgartner does discuss "support members having different dimensions" it is only in the context of increasing packing density. See, col. 2, ll. 8-9. Baumgartner further states that "the number and dimension of the support members 7 can be varied at random according to the dimensions given and the shape of the cavity 5 to be filled...". Col. 3, ll. 61-64 [emphasis added]. Baumgartner does not recognize "top" and "bottom" elements and therefore does not contemplate the need for or benefit of these elements having a greater area than the intermediate elements. Moreover, as explained above, Baumgartner essentially randomly jams each ball support element into the space, so it is not known which or whether any particular support element will be pushed into a top or bottom position. Baumgartner cannot contemplate specifically identifying a larger area top and bottom element and therefore cannot render claims 196 and 197 obvious.

Dependent claim 211 was rejected as obvious in view of Baumgartner and Kuslich. The Kuslich reference was cited for its disclosure of bone replacement materials. It was argued that any particular material could be selected "in order to provide a desired physiological response and improve the outcome of the surgical procedure." However,

Applicants claim 192 and dependent claim 211 are not directed to any "physiological response" – the claims are directed to a method of "providing interbody spinal fusion." The bone filler material defined in claim 211 fuses the upper and lower vertebral bodies. Fusion is exactly contrary to the purpose of the Baumgartner disk prosthesis. The ball support members of Baumgartner are elastic and are intended as a replacement for the removed disk material (col. 3, ll. 47-52) and as a compact elastic support structure (col. 5, ll. 57-60). Fusion or the introduction of bone filler material into the disc space would completely frustrate the purpose and function of the Baumgartner implant. Consequently, whether or not it would be obvious to introduce a material to achieve a "desired physiological response" is not relevant to the suggested obviousness rejection. What is relevant is that it would not be obvious to introduce a bone filler into the Baumgartner implant because to do so would destroy the function of the implant. It is therefore believed that claim 211 is patentable over the cited combination.

With respect to the suggestion of filler material, Applicants note that U.S. Patent No. 5,756,127 to Grisoni et al., discloses a string of implantable beads that look similar to the balls in FIG. 7 of Baumgartner. Grisoni does discuss placing the beads in a bone void to repair the void, and more specifically discloses adding bone graft for promoting bone growth. Col. 5, ll. 28-34. While Grisoni does disclose bone growth material, this disclosure does not alter the fact that any fusion or bone growth in the disc space would completely frustrate the purpose and function of the Baumgartner implant. Thus, even if Grisoni is combined with Baumgartner, Applicants' claim 211 is still non-obvious and patentable.

The other independent claims 212 was also rejected as anticipated by Baumgartner. Applicants have amended claim 212 to add the step of providing a fusion promoting composition between the vertebral bodies in contact with the elements. This limitation is similar to dependent claim 215 in that bone filler is one type of fusion promoting composition contemplated by the present invention. Claim 215 has been amended accordingly. It is noted that claim 215 was rejected as obvious in view of the combination of Baumgartner with Kuslich. As explained in detail above, providing a fusion promoting composition would completely destroy the function of the elastic ball support elements in Baumgartner. It is well-settled that a *prima facie* case for obviousness cannot be found where the suggested combination would frustrate the purpose or destroy the function of the underlying reference, in this case the Baumgartner patent.

Thus, claim 212 as amended is believed to be patentable over the cited art, either individually or in combination. Dependent claims 213-224 likewise benefit from the patentability of claim 212 (although claims 216 and 218-221 have already been deemed allowable).

In view of the foregoing amendments and arguments, it is believed that the substantive rejections have been traversed and that claims 192-197 and 209-225 are in condition for allowance. Consequently, action toward that end hereby requested. The Examiner is invited to contact the undersigned agent of record in the event that issues arise that may be addressed in a telephonic interview to place the application in condition for allowance.

April 16, 2007

Respectfully submitted,

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